

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and
GLOBAL LIFE SCIENCES
SOLUTIONS USA, LLC,

Plaintiffs,

V.

BIO-RAD LABORATORIES, INC.,

Defendant.

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF ITS MOTION FOR
SUMMARY JUDGMENT OF INFRINGEMENT OF
CLAIM 1 OF U.S. PATENT NO. 9,671,420,
CLAIM 1 OF U.S. PATENT NO. 9,709,589,
CLAIM 14 OF U.S. PATENT NO. 9,709,591, AND
CLAIM 16 OF U.S. PATENT NO. RE47,124**

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I. NATURE AND STAGE OF THE PROCEEDING

Bio-Rad initiated this action on November 30, 2018 (D.I. 1). On July 24, 2019, the Court consolidated this case with a case brought by Cytiva that had been transferred from the Southern District of New York, which had been filed there on September 2, 2014 (D.I. 46). Cytiva is presently asserting claims 1, 4-9, 15, 25, 27, 29, 30 of U.S. Patent 9,671,420 (“the ’420 Patent”) (Ex. 35), claims 1, 2, 4, 6-10, 12, 13-14, 19-21, 23-27, 30 of U.S. Patent 9,709,589 (“the ’589 Patent”) (Ex. 32), claims 1-4, 10, 12-14, 17-18 of U.S. Patent 9,709,590 (“the ’590 patent”) (Ex. 33), claims 9, 14, 26-27 of U.S. Patent 9,709,591 (“the ’591 patent”) (Ex. 34), and claims 16, 19-20, 22, 25, 27-28, 30, 33-35 of U.S. Patent RE47,124 (“the ’RE124 Patent”) (Ex. 36).

This Motion seeks summary judgment under Fed. R. Civ. P. 56 that Bio-Rad infringes claim 1 of the ’420 patent, claim 1 of the ’589 patent, claim 14 of the ’591 patent and claim 16 of the ’RE124 patent. The undisputed facts are presented in Plaintiffs’ Concise Statement of Undisputed Facts.

II. SUMMARY OF ARGUMENT

1. There is no genuine factual dispute that Bio-Rad’s technical specifications, drawings, product manuals, and deposition testimony from its witnesses all confirm that all models of its NGC automated liquid chromatography system infringe claim 1 of the ’420 patent, claim 1 of the ’589 patent, claim 14 of

the '591 patent and claim 16 of the 'RE124 patent. As outlined herein and in Plaintiffs' co-pending *Daubert* motion, Bio-Rad's defenses rely on either improper attempts to reargue claim construction issues previously decided by this Court or by belatedly (and incorrectly) raising claim construction issues.

III. STATEMENT OF FACTS

A. Cytiva

Cytiva develops and sells life science technologies and services for the pharmaceutical industry. Cytiva is a world leader in chromatography systems and has deep knowledge of chromatography and the challenges users of such systems face. It was this knowledge coupled with Cytiva's ingenuity that led to the inventions at issue in this case.

B. Liquid Chromatography Systems

Chromatography is a method for separating chemical components. There are many different kinds of chromatography. Common to many types of chromatography is that chemical components (called the mobile phase) are separated by flowing them over a stationary material (called the stationary phase) for which those chemical components have varying degrees of affinity, *i.e.* they are attracted to greater or lesser degrees to the stationary phase. These differing degrees of affinity allow some of the chemical components to move faster than others, separating the originally mixed chemical compounds into discrete bands. When performed with

liquid chemical compounds, this process is called liquid chromatography. Modern liquid chromatography is a complicated process, used for either diagnostics—analyzing the chemical components of a fluid, or production—separating some desired chemical component from a fluid for the purpose of collecting that component or components for subsequent use. Both applications of liquid chromatography require many different fluid operations to be performed precisely in succession in order for the chromatography to succeed. Declaration of Steven Wereley (“Wereley”), ¶47.¹ ²

Prior to the invention, automated liquid chromatography systems sold by Cytiva, Bio-Rad, and others were complicated, as well as difficult to modify and use. Cytiva’s development documents for the patented systems demonstrate that the goal of the development activities were systems that would have [REDACTED]

[REDACTED]

[REDACTED]

¹ All cited factual materials are appended to the Concise Statement Of Undisputed Facts.

² Dr. Wereley’s declaration incorporates material from his opening, rebuttal and reply expert reports.

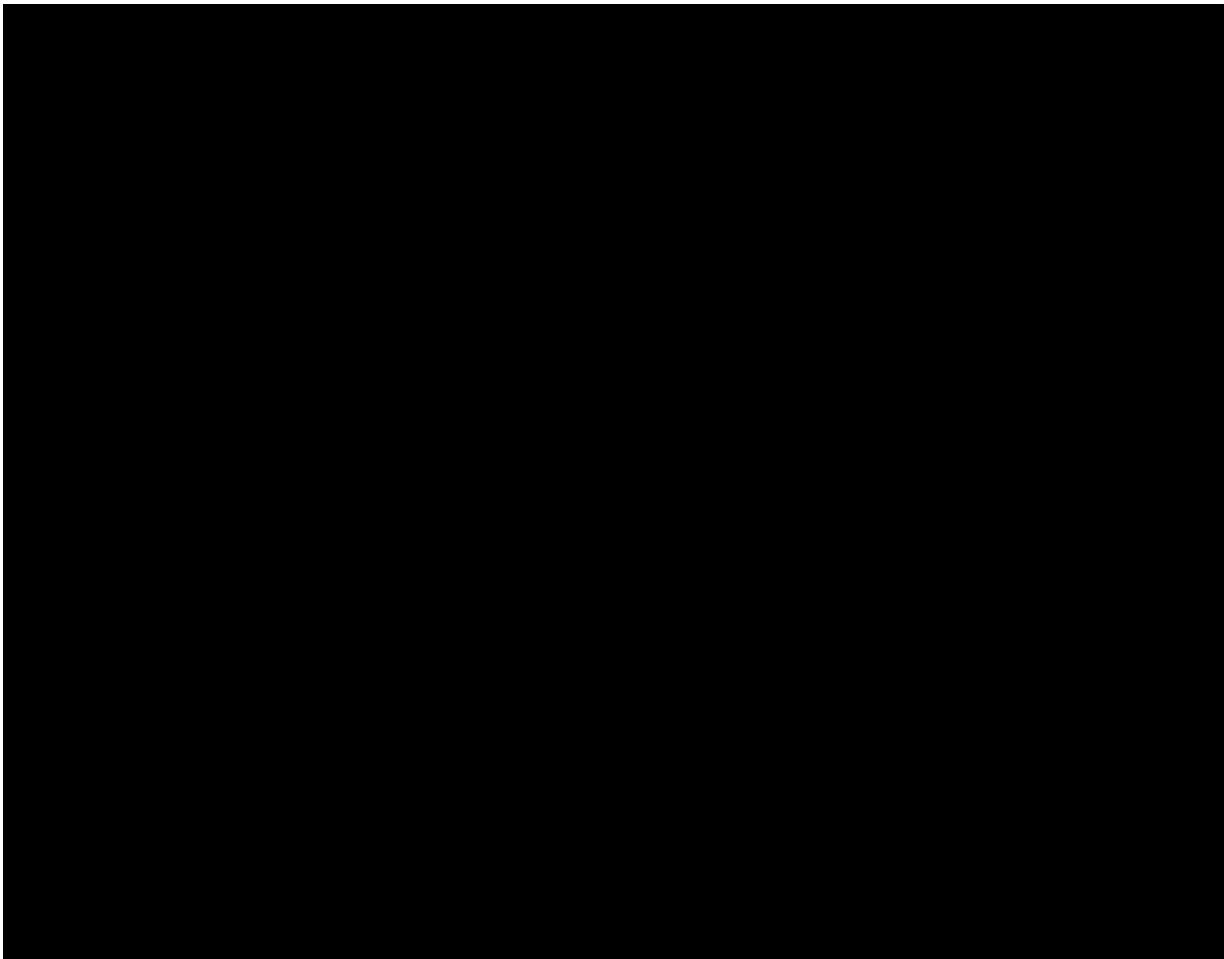
Wereley, ¶48; Ex. 1³ (GEHCDEL127450 at 52).

Similarly, before introducing its NGC systems, Bio-Rad sold a system called “DuoFlow.” During their depositions in this case, various Bio-Rad personnel testified that the DuoFlow was [REDACTED]

[REDACTED] Ex. 2 (Iovanni Tr.) 64:8-20, 201:6-202.22;

Ex. 3 (Chapman Tr.) 489:22-490:17. This September 2009 Bio-Rad presentation shows that Bio-Rad recognized this:

³ “Ex.” refers to exhibits attached to the Concise Statement Of Undisputed Facts, referred to in the Wereley Declaration and Declaration of Jeffrey A. Miller In Support of this motion.

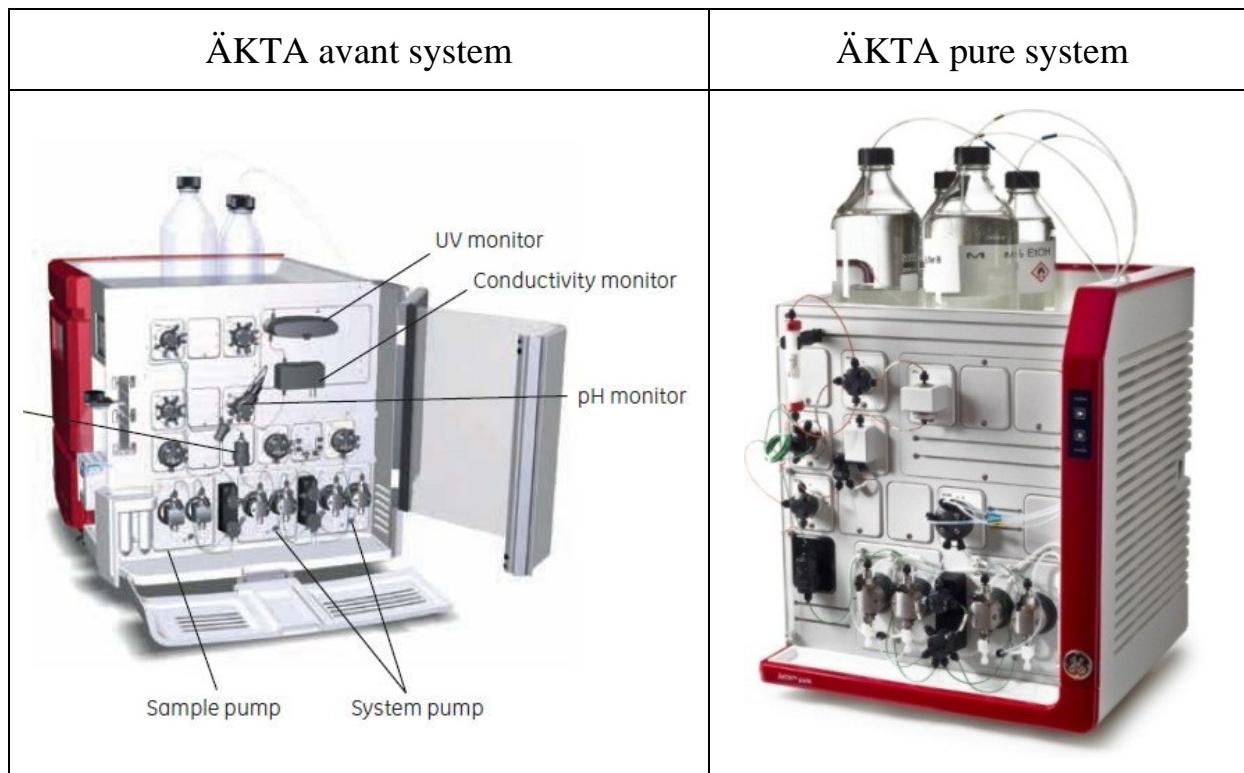


Wereley, ¶¶50-51; Ex. 4 (BRGE00016967).

The claims in this motion recite automated liquid chromatography systems having a unique architecture, including a housing with receiving positions into which interchangeable modular components can be inserted. These interchangeable modular component also have a unique architecture that allow them to be “readily interchangeable,” which the patents state “provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, *e.g.* in order to optimize the

fluid path for a specific experimental setup.” 5:53-57.⁴ Important aspects of the inventions contribute to this important functionality. For example, the modules have their own CPU that allows each to independently perform operations in response to instructions that it receives from a master control unit. Wereley, ¶31.

Cytiva uses the claimed inventions in its ÄKTA avant and ÄKTA pure products. Wereley, ¶32. Photographs of each are shown below:



C. Bio-Rad’s Accused NGC System

Bio-Rad’s NGC system is made up of four main models: Quest, Scout, Discover and Discover Pro. Ex. 5, p. 87-88; Wereley, ¶¶54-59. Regardless of model,

⁴ For convenience, Cytiva cites to the ’589 patent (Ex. 32) herein.

the NGC system is remarkably similar to both Cytiva's products and the system disclosed and claimed, as is seen by comparing the system shown in Fig. 1 from the patents with various NGC models:

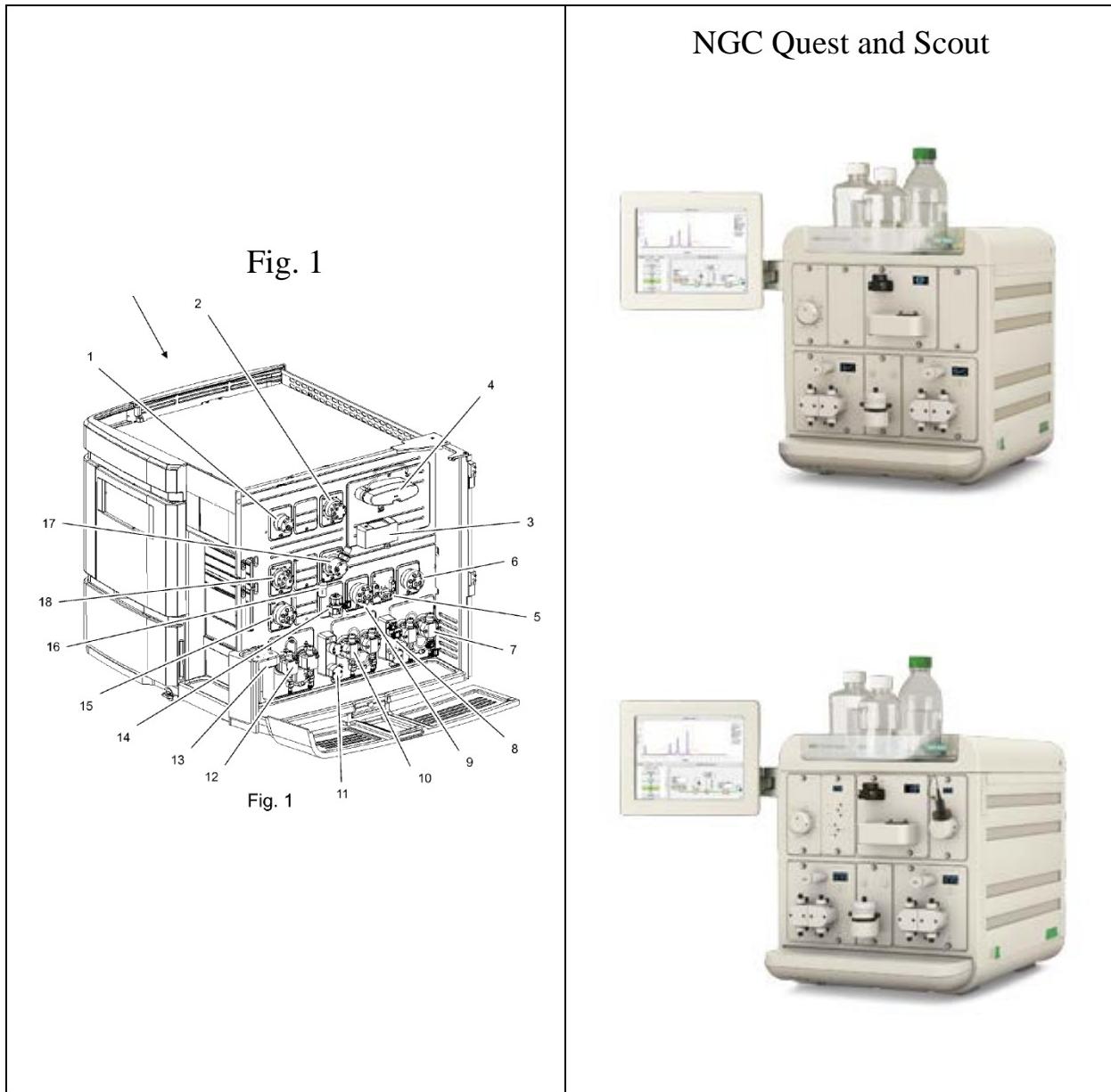




Fig. 1 and <https://www.bio-rad.com/en-us/sku/7880002-ngc-quest-100-chromatography-system?ID=7880002>, <https://www.bio-rad.com/en-us/sku/7880006-ngc-scout-100-chromatography-system?ID=7880006>,
<https://www.bio-rad.com/en-us/sku/7880010-ngc-discover-100-chromatography-system?ID=7880010>, <https://www.bio-rad.com/en-us/sku/7880012-ngc-discover-100-pro-chromatography-system?ID=7880012>.

Cytiva's Concise Statement of Undisputed Facts contains the undisputed, material facts that support this motion.

IV. LEGAL STANDARD

Summary judgment is intended to isolate and dispose of factually unsupported claims or defenses. *See Celotex Corp. v. Catrett*, 4777 U.S. 317, 327 (1986). Summary judgment is proper if the pleadings, the discovery and disclosure materials

in the record, and any affidavits “[show] that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A dispute about a material fact is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The trial court must solve all reasonable doubts in favor of the party opposing the motion for summary judgment. *Country Floors, Inc. v. A Partnership Composed of Gepner and Ford*, 930 F.2d 1056, 1061 (3d Cir. 1991). The party moving for summary judgment has the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Id.* at 247.

V. CYTIVA IS ENTITLED TO SUMMARY JUDGMENT OF INFRINGEMENT

“A determination of infringement involves two steps.” *Innovention Toys, LLC v. MGA Entm’t, Inc.*, 637 F.3d 1314, 1318 (Fed. Cir. 2011). “First, the court determines the scope and meaning of the asserted patent claims,” which the Court has already done in this case through its claim construction ruling. *Id.* “The court then compares the properly construed claims to the allegedly infringing device to determine whether all of the claim limitations are present.” *Id.* at 1318-19. If all of the claim elements are present in the accused instrumentality, that instrumentality is covered by that patent claim. *Electro Sci. Indus., Inc. v. Gen. Scanning*, 247 F.3d, 1341, 1349-55 (Fed. Cir. 2001); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d

1342, 1358-59 (Fed. Cir. 1998). Infringement exists as long as “every element or its substantial equivalent [is present] in the accused device.” *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1568 (Fed. Cir. 1996) (internal quotation marks omitted) (citation omitted).

A. In All Relevant Aspects, The Four NGC Models Are Substantively The Same

Bio-Rad’s NGC system is made up of four main models: Quest, Scout, Discover and Discover Pro. These models have the same architecture and can have the same modules installed therein. The differences between models relate to the modules that are included as standard equipment, whether they include an expansion housing and if so, how many. Ex. 5, p. 87-88; Wereley, ¶¶54-59. The below analysis applied to all NGC models.

B. Cytiva is Entitled to Summary Judgment that Bio-Rad Infringes Claim 1 of the ’420 Patent

1. “[a]n automated liquid chromatography system”

There is no genuine dispute that all NGC models contain this limitation. First, the NGC’s Instrument Guide states that it is a liquid chromatography system, and that the system “rapidly automates” the purification of biomolecules:



1 Introduction

The NGC chromatography systems are preparative systems designed to rapidly automate the purification of biomolecules. The flexible, modular, and economical design makes NGC the instrument of choice for method development and scale-up. It is available in six preplumbed, factory-tested configurations at two different flow ranges. Each preconfigured system can be further customized and upgraded by adding valves, detectors, or pumps in order to meet specific application needs. Any system can be configured for either low flow rate or high flow rate operation by simply changing the system pump modules. As a result, a single hardware platform can be modified as the application need and scale change.

Wereley, ¶60; Ex. 5, p. 11. Additionally, a Bio-Rad document created during development of the accused NGC product states that [REDACTED]

[REDACTED] Wereley, ¶61; Ex. 6 (BRGE00065119). The author, Dr. Mavandadi, explained that [REDACTED]

[REDACTED] *See* Ex. 7 (Mavandadi Tr.) 106:5-15.

Moreover, automated liquid chromatography systems have certain components for performing liquid chromatography, including an injection valve, a pump, an inline detector that can measure the relevant characteristics of the liquid exiting the chromatography column, and control software for processing, displaying, and/or storing the results, which operate without manual intervention. Wereley, ¶63.

There is no dispute that Bio-Rad's NGC has each of these, as all models come standard with a sample inject valve module,⁵ two system pump modules⁶, a UV monitor module that measures characteristics of the liquid exiting the chromatography column,⁷ and control software for automatically controlling the liquid chromatography system.⁸ *See Sections V.B.1 and V.B.3 and Wereley, ¶¶60-64, 73-82.*

Bio-Rad's expert, Dr. Bruce Gale, agreed that the NGC system can perform automated liquid chromatography. *See Ex. 8 (Gale Tr.) 353:7-355:12.* Accordingly, there is no genuine dispute that this limitation is met.

2. “a housing”

There is no dispute—genuine or otherwise—that all NGC models contain this limitation. Bio-Rad documents have images and schematics of the NGC, which demonstrate that each NGC model has a housing. *See Wereley, ¶¶65-72.*

⁵ Wereley, ¶88; (Ex. 5, pp. 37, 87); Ex. 8 (Gale Tr.) 355:13-16.

⁶ Wereley, ¶87; (Ex. 5, pp. 28, 87).

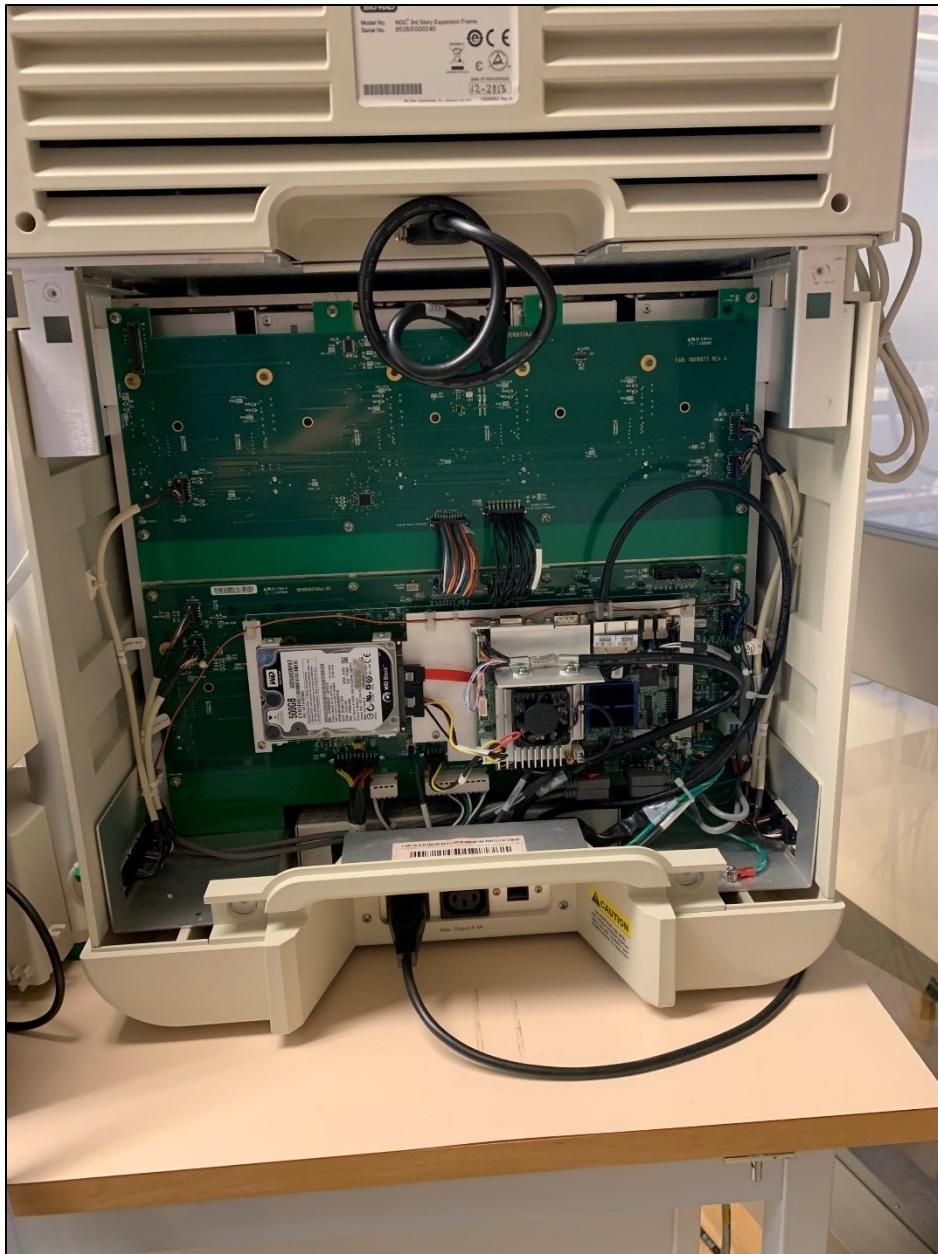
⁷ Wereley, ¶172; Ex. 5, pp. 65 (“The UV detectors measure the UV absorbance of biomolecules as they elute through the column. The conductivity monitor measures the ionic strength (salt concentration) of buffers.”); *see also id.*, 66-72, 87); Ex. 8 (Gale Tr.) 357:2-359:2).

⁸ Ex. 8 (Gale Tr.) 356:3-7; Ex. 3 (Chapman Tr.) 333:18-334::2; *see also* Ex. 9 (User’s Guide), p. 21.

Additionally, an NGC specification demonstrates that the system has a “main enclosure,” which a Bio-Rad witness, Mr. Wayne Bland, explains is “basically the box” that holds the modules along with the electrical components needed to connect each module to the system. *See Ex. 10 (Bland Tr.) 86:2-86:17.* Furthermore, another NGC specification explains that the “main enclosure” “shall be able to accommodate 10 ‘single slot’ peripherals in a 5 x 2 grid arrangements” and that “[d]ouble slot devices (such as pumps or detectors) can be accommodated by removing the vertical divider between adjacent slots.” *See Wereley, ¶71, Ex. 11 (BRGEDEL445194).* Another Bio-Rad witness, Mr. Philip Chapman, explained that the main system enclosure is “the main chassis that houses the various valves and pumps.” *See Ex. 3 (Chapman Tr.) 541:6-541:22.*

3. “a master control unit connected to a system bus”

There is no genuine dispute that all NGC models contain this limitation. All have a single board computer that controls the system (*see Ex. 10 (Bland Tr.) 36:1-36:13*) and the single board computer is installed inside the housing (*see Ex. 10 (Bland Tr.) 37:8-38:18*). This photograph shows the single board computer:



See Wereley, ¶78. Bio-Rad specifications for each of the modules demonstrate that each module communicates with the single board computer via a bus, which Bio-Rad witnesses confirmed. *See* Wereley, ¶79-80; Ex. 13 (BRGE0096083); Ex. 14 (BRGEDEL000450748); Ex. 10 (Bland Tr.) 144:1-11.

4. “three or more fluid handling units arranged as interchangeable modular components”

There is no genuine dispute that all NGC models contain this limitation. The Court construed “interchangeable modular component” as a “component that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another component.” D.I. 75-1, at 2. All NGC models come with two system pump modules, a sample inject module, and a UV detector module. Wereley, ¶¶85-88; Ex. 5, p. 87.⁹

Each of these modules can be “inserted into and removed from positions in the housing.” Bio-Rad’s Instrument guide explains that “[t]he position of the module on the system can be changed to optimize the placement and minimize the length of tubing.” Wereley, ¶89; Ex. 5, p. 19. An NGC specification specifies that modules

[REDACTED] (Wereley, ¶89, Ex. 12

(BRGEDEL401642) and that the system requires [REDACTED] (Wereley, ¶90; Ex. 12 (BRGEDEL401629). Furthermore, each module “has a standardized size and shape that allows it to be exchanged with another component.” Bio-Rad’s documentation notes that its modules can be “single-side” and “double-wide” (Ex. 5, pp. 237-238), and thus have a standardized size and shape. This was confirmed

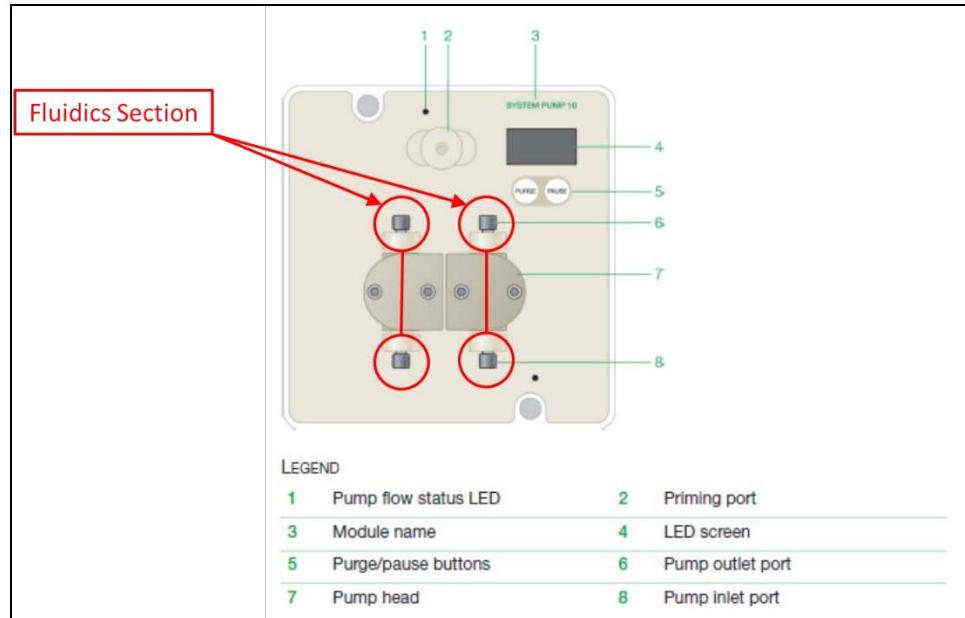
⁹ For purposes of this claim, Cytiva need only show that the two system pump modules and the sample inject valve module are “interchangeable modular components.”

by Bio-Rad's Mr. Bland, who testified that "the modules are fully interchangeable with all bays within the -- the housing, so they could be moved in any location as many times as a user may want to configure them." Wereley, ¶89; Ex. 10 (Bland Tr.) 98:13-101:1.

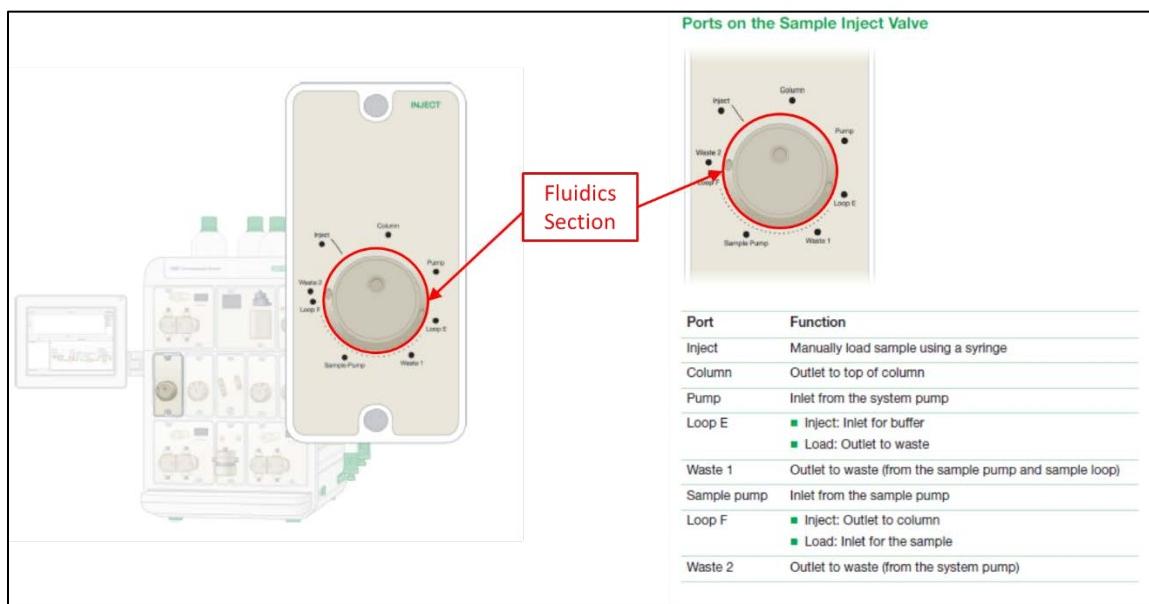
5. "(i) an external fluidics section,"

There is no genuine dispute that all NGC models contain this limitation. The Court construed "fluidics section" as "a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components." D.I. 75-1, at 3. Each module's specification states that [REDACTED]

[REDACTED] (Wereley, ¶97, Exs. 13 (BRGE96090), 14 (BRGEDEL450753)). A Bio-Rad employee, Mr. Philip Chapman, confirmed that each of the modules met this specification. *See* Wereley, ¶98; Ex. 3 (Chapman Tr. 529:12-530:17, 528:16-529:10). The figures below excerpted from Bio-Rad's documentation have been annotated to show the external fluidics section. This annotation shows the fluidics section of the two system pump modules:



Wereley, ¶100; Ex. 5, p. 29. This annotation shows the fluidics section of the sample inject valve module:



Wereley, ¶103; Ex. 5, pp 37-38. Fluid flow in the valve itself is shown in the below Bio-Rad figures:

Valve Position	Explanation
Manual Load Loop/System Pump to Column	<ul style="list-style-type: none"> ■ Directs system pump flow directly toward the column ■ Aligns the sample loop with manual injection port so that sample can be manually filled into the loop using a syringe. Excess sample goes out waste port (W1) ■ Chromatogram x-axis based on system pump flow rate
System Pump Inject Loop/Sample Pump Waste	<ul style="list-style-type: none"> ■ Directs system pump flow through the sample loop to load the sample from the loop onto the column ■ Directs sample pump flow to waste (W2) ■ Chromatogram x-axis based on system pump flow rate

Wereley, ¶103; Ex. 5, p. 40.

The Court’s construction requires that the fluidics section “not include non-fluidics components.” While the annotated drawings are clear that the fluidics section contains only components involved in fluid transmission, a person of ordinary skill in the art (“POSITA”) would understand that to the extent there are non-fluidic components outside of the claimed non-fluidics section, those electronics are not part of the fluidics section. *See Wereley, ¶¶105-106.*

Dr. Gale does not refute that the fluidics components identified by Dr. Wereley do not contain non-fluidics components (*i.e.*, that there are no electronics

in the fluid paths). Rather, Dr. Gale's criticism appears to be that because there are electronic components integrated into the panel member, the fluidics components are not "separated" from the electronic components integrated into the panel member and thus are not the claimed fluidics section. *See, e.g.*, Ex. 15 (Gale Rebuttal Report), ¶127. However, as explained in Plaintiffs' *Daubert* motion, filed herewith, this opinion is contrary to the Court's claim construction. *See* Ex. 37 (*Markman* Tr.) 97:16-25, 100:14-23, and 103:8-13. Accordingly, there is no genuine dispute that all NGC models have a fluidics section.

6. "(ii) an internal non-fluidics section"

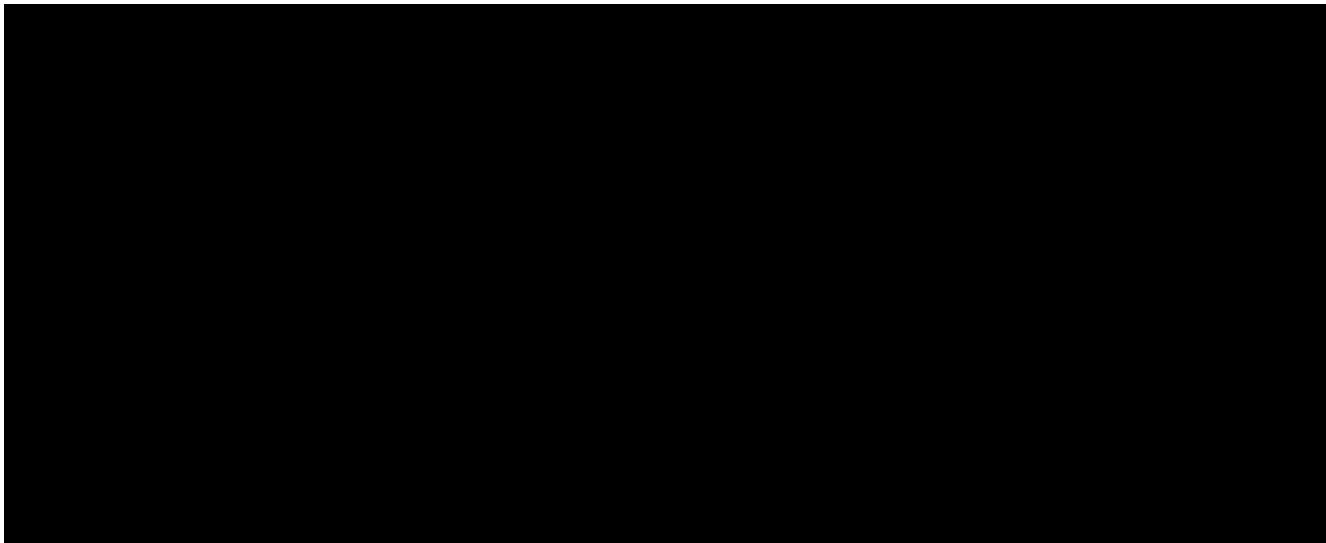
There is no genuine dispute that all NGC models contain this limitation. The Court construed this term as "a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics component." D.I. 75-1, at 3. The specifications for the pump modules and the sample inject module state that [REDACTED]

[REDACTED] and [REDACTED]

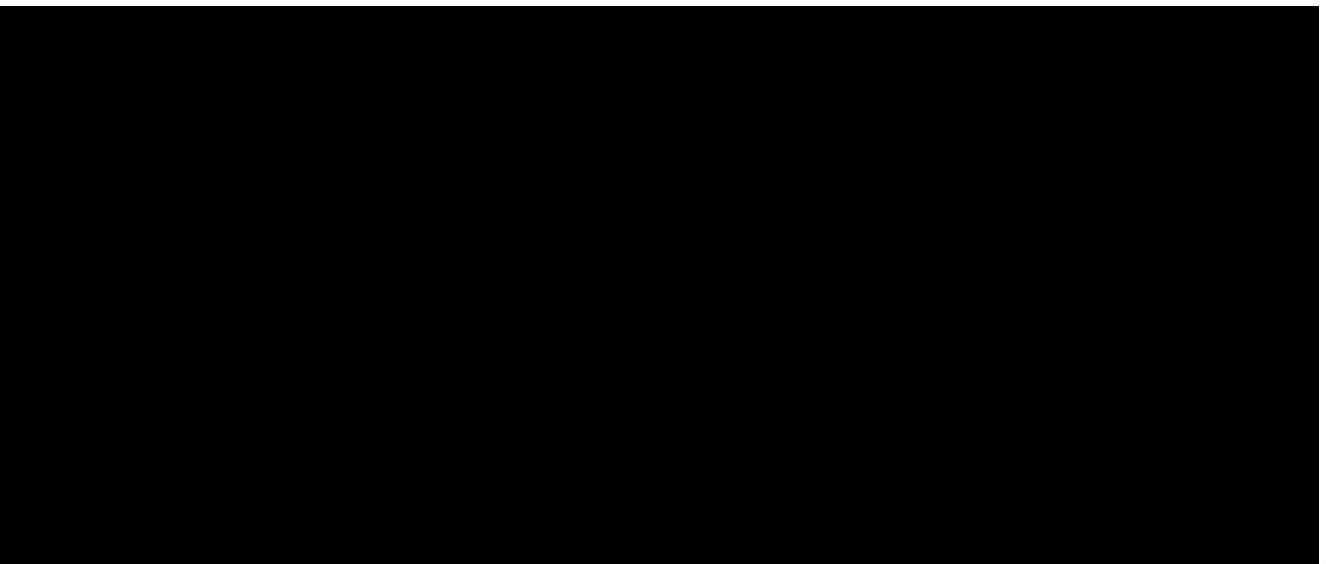
[REDACTED]
[REDACTED]

[REDACTED] Wereley, ¶110; Ex. 13 (BRGE96090), Ex. 14 (BRGEDEL450753). Mr. Chapman confirmed that these specifications are met. Wereley, ¶111; Ex. 3 (Chapman Tr.) 529:12-530:17, 528:16-529:10. NGC specifications annotated by Dr.

Wereley point to the internal non-fluidics section of NGC modules and further illustrate that the section contains no fluidic components. The following shows the non-fluidics section of the two system pump modules:



Wereley, ¶114; Ex. 16 (BRGEDEL317444, BRGEDEL317555).The following shows the non-fluidics section of the sample inject valve:

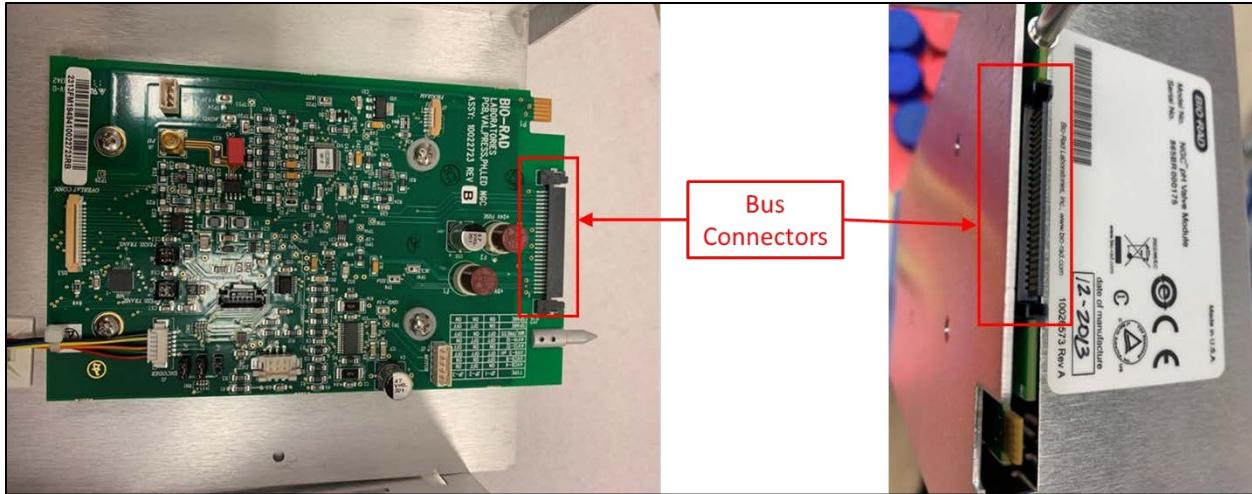


Wereley, ¶115; Ex. 16 (BRGEDEL317453-317454, BRGEDEL317564) .

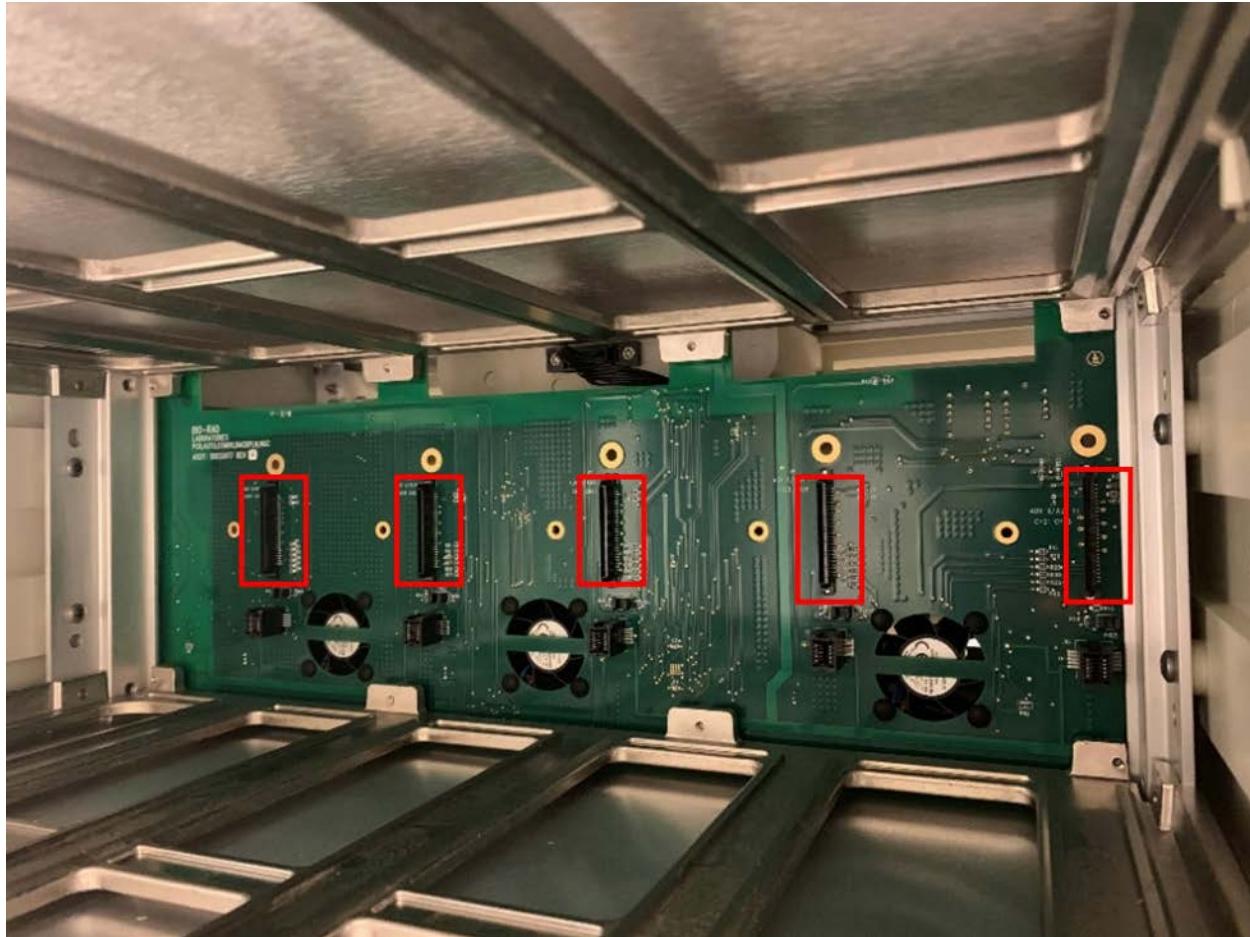
Once again, Dr. Gale does not take issue with whether the non-fluidic section, as identified by Dr. Wereley, contains fluidic components. Rather, he criticizes how Dr. Wereley maps the non-fluidics section onto the NGC. Dr. Gale points to electronics integrated into the panel member, such as LED lights, a PCB, and a ribbon line, and claims that those non-fluidic components must be part of the non-fluidics section, and thus the non-fluidics section is not separated from the non-fluidics section by the panel member. *See* Ex. 15 (Gale Rebuttal Report) ¶¶117, 122-123. However, just as he did with the fluidics section, Dr. Gale ignores the Court's construction, which does not require *all* non-fluidic components be part of the non-fluidics section. *See* Ex. 37 (*Markman* Tr.) 97:16-25, 100:14-23, and 103:8-13. Accordingly, when viewed in light of the Court's construction, all NGC models have the claimed non-fluidics section.

7. “including a bus connector for directly connecting the interchangeable modular component with the system bus, and”

There is no genuine dispute that all NGC models contain this limitation. Bio-Rad's specifications as well as photographs of the accused modules taken by Cytiva demonstrate that each module of the NGC meets this limitation. *See* Wereley, ¶¶117-127. Below are photographs showing the connector on a valve module that is annotated to show the connector:



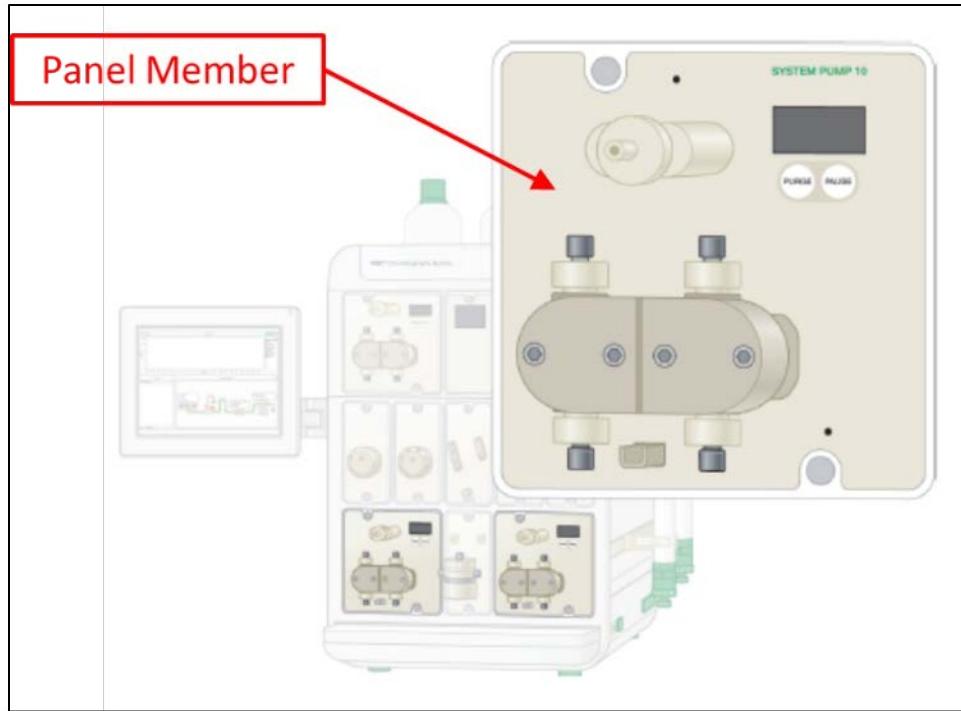
See Wereley, ¶120. The bus connectors on each module are “directly connected” to each of the modules “with the system bus.” As seen below, the backplane in the NGC system has connectors (annotated with red rectangles) that receive and mate with the bus connectors on each module:



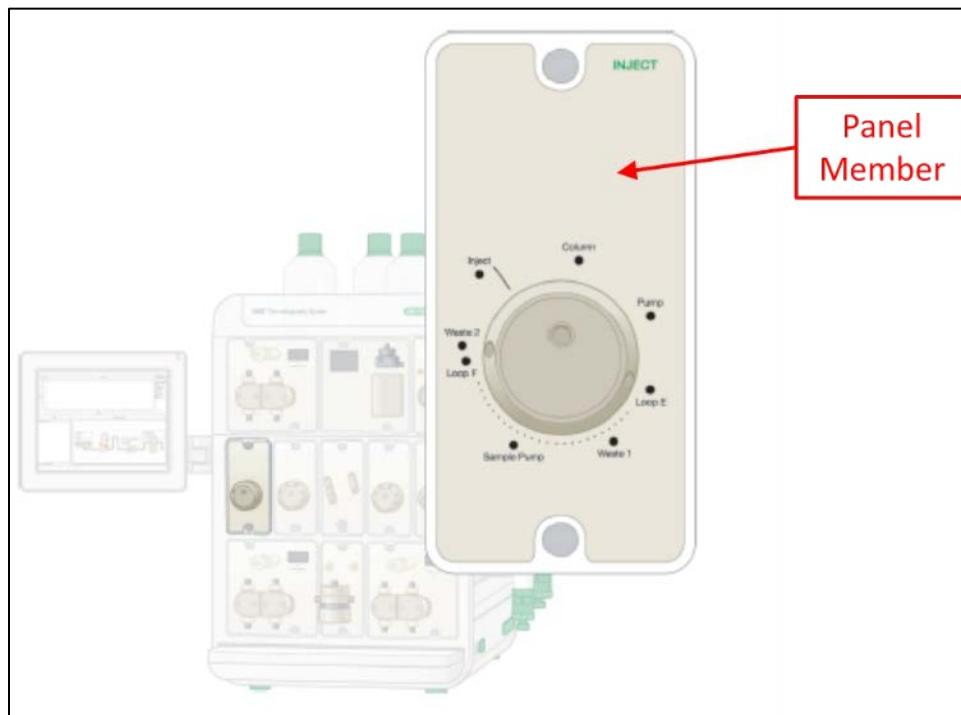
See Wereley, ¶122.

8. “(iii) a panel member arranged to separate the fluidics section from the non-fluidics section;”

There is no genuine dispute that all NGC models contain this limitation. Bio-Rad’s Assembly Procedures and User Manual demonstrate that there is a panel member that separates an internal non-fluidics section from an external fluidics section. Below, a figure from Bio-Rad’s Instrument Guide has been annotated to show the recited panel member for the two system pump modules present in all NGC models:



Wereley, ¶¶129-130; Ex. 5, p. 28. Similarly, the panel member for the sample inject valve module is identified in this annotated figure:



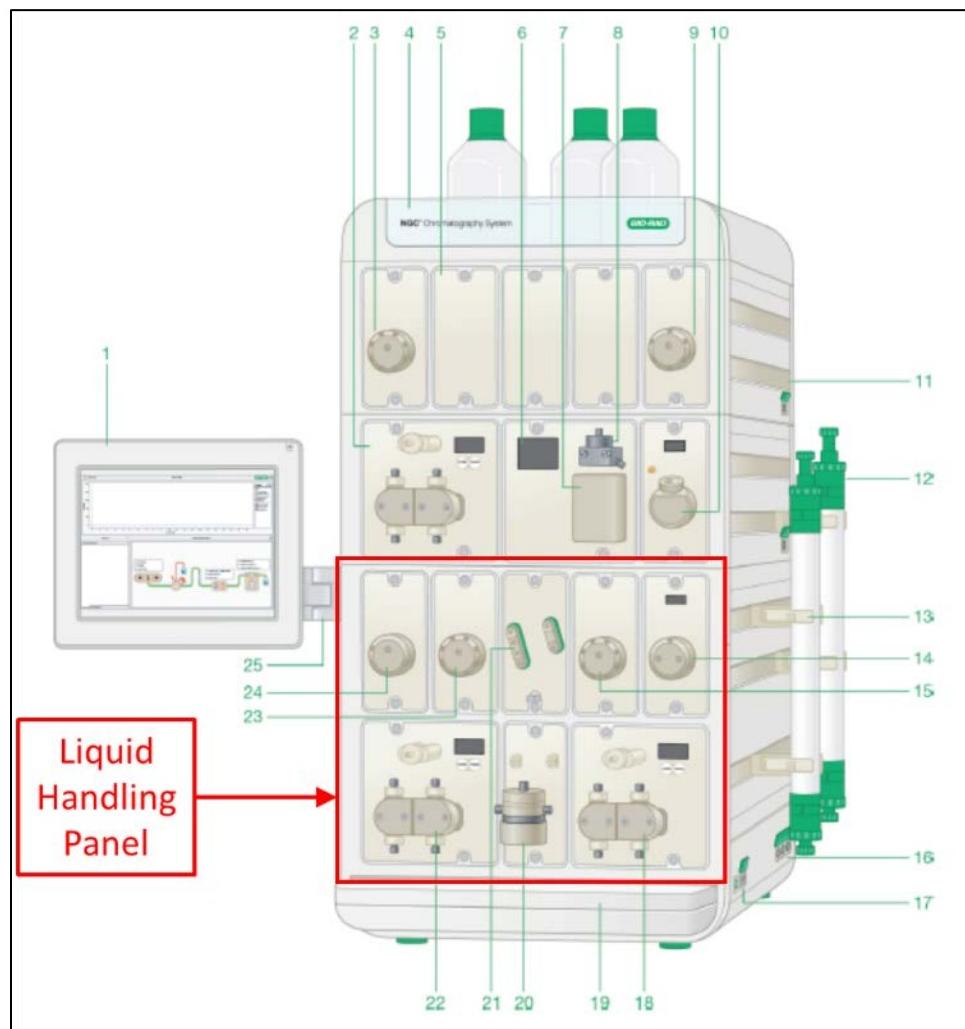
Wereley, ¶131; Ex. 5, p. 37.

Additionally, Bio-Rad witnesses confirmed that the structure identified by Dr. Wereley as the panel member is comprised of a “front plate” and an “overlay” (*see* Ex. 10 (Bland Tr.) 151:4-155:21) and that the structure has [REDACTED]
[REDACTED]
[REDACTED] (Ex. 3 (Chapman Tr.) 388:18-21).

Dr. Gale does not refute that the structure Dr. Wereley identifies as the claimed panel member separates the non-fluidics section and fluidics section, as they are identified by Dr. Wereley. Rather, Dr. Gale opines that because there are non-fluidic components integrated into the structure Dr. Wereley identifies as the panel member, those non-fluidics components are not separated from the fluidics section. *See, e.g.*, Ex. 15 (Gale Rebuttal Report) ¶78. However, once again, Dr. Gale ignores the Court’s construction that allows for “other sections.” *See* Ex. 37 (*Markman* Tr.) 103:8-13. The panel member is certainly a different section from the fluidics section and, as such, can contain electronics. Accordingly, there is no genuine dispute that the NGC modules have a panel member arranged to separate the internal non-fluidics section from the external non-fluidics section.

- 9. “wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing”**

There is no genuine dispute that all NGC models contain this limitation. First, the housing of each NGC model has a front panel with multiple positions into which modules can be inserted, which is seen in this annotated figure from Bio-Rad's Instrument Guide:



See Wereley, ¶138; Ex. 5, p. 22. Bio-Rad's Instrument Guide also demonstrates how each receiving position may be converted from a single-wide to a double-wide position in order to accommodate different sized modules. *Id.*, p. 237-238. Next, these receiving positions are arranged in a two dimensional array. *See* Wereley, ¶¶139-140. As explained above, in Section V.B.5, the two system pump modules and the sample inject valve module each have an external fluidics section and an internal non-fluidics section. When the modules are inserted into the housing the fluidics section and non-fluidic section are external and internal to the housing, respectively.

Dr. Gale neither disputes that the housing of each NGC model has receiving positions arranged in a two dimensional array nor that the non-fluidics section and fluidics section, as identified by Dr. Wereley, are internal and external to the housing, respectively. Accordingly, there is no genuine dispute that this limitation is met.

10. “wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus”

There is no genuine dispute that all NGC models contain this limitation. Photographs taken by Cytiva demonstrate that the NGC has a “backplane” that the back of each module abuts upon insertion into the housing. *See* Wereley, ¶144. The backplane contains a series of connectors that mate with the connector on the back

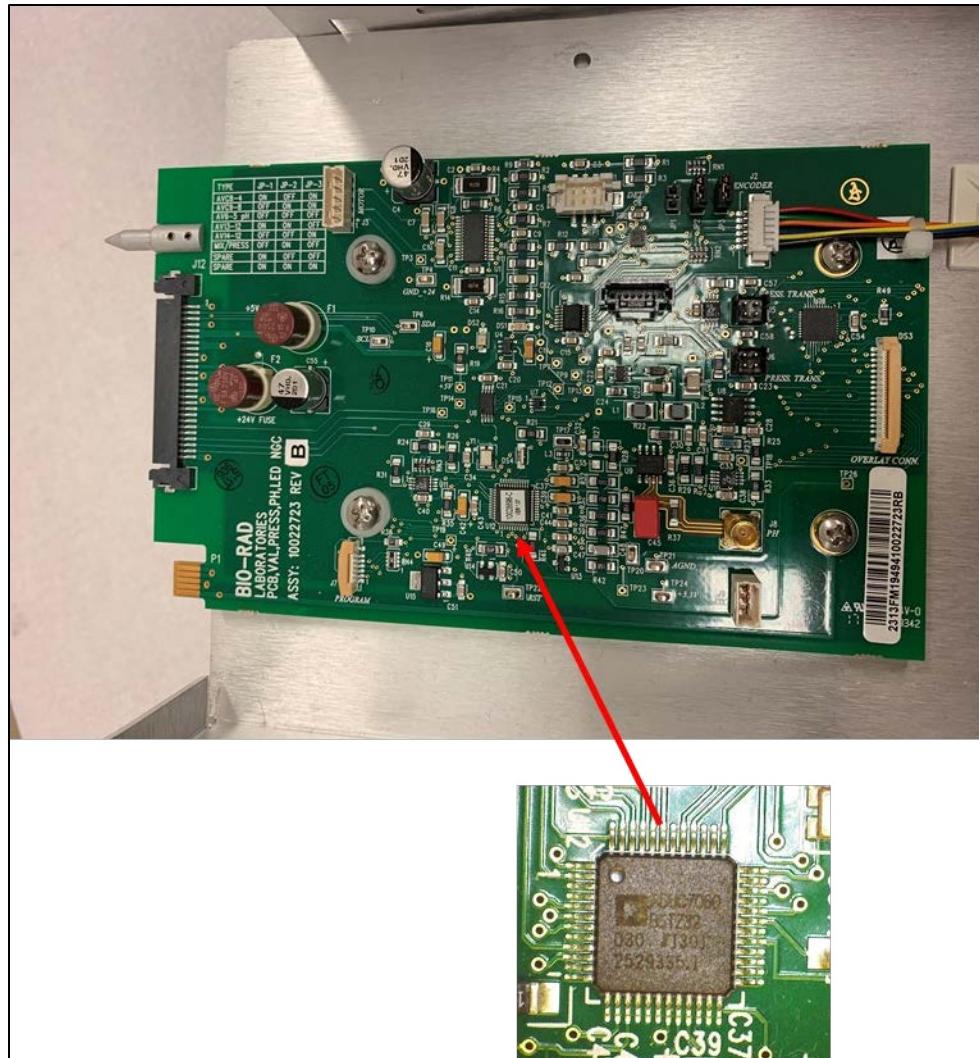
of an inserted module, plainly demonstrating that these connectors are “complementary.” *Id.* at ¶¶145-146. Testimony from a Bio-Rad witness confirms that these complementary connectors “connect[] the bus connector of the interchangeable modular component inserted therein to said system bus.” *See* Ex. 10 (Bland Tr.) 144:1-11 (explaining that [REDACTED]
[REDACTED]).

11. “wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus”

There is no genuine dispute that all NGC models contain this limitation. First, each NGC module has a CPU. The parties agreed that the term “CPU” should be construed as “central processing unit.” D.I. 75-1, at 1. Bio-Rad’s specifications for the system pump modules and the sample inject valve module state that each module

[REDACTED]

[REDACTED] Wereley, ¶¶150-151, Ex. 13 (BRGE0096081), Ex. 14 (BRGEDEL000450746)). Testimony from one of Bio-Rad’s witnesses confirmed that the [REDACTED] is a CPU (*see* Ex. 10 (Bland Tr.) 105:2-17) and Bio-Rad’s firmware specification describes the [REDACTED] (*see* Wereley, ¶155, Ex. 17 (BRGEDEL98274)). Additionally, a photograph of a circuit board inside Bio-Rad NGC module demonstrates the presence of a CPU:



Wereley, ¶153. The manufacturer of this part, Analog Devices, confirms that it has a CPU:

PROCESSOR REFERENCE PERIPHERALS INTERRUPT SYSTEM

There are 15 interrupt sources on the ADuC7060/ADuC7061 that are controlled by the interrupt controller. All interrupts are generated from the on-chip peripherals, except for the software interrupt (SWI), which is programmable by the user. The ARM7TDMI CPU core recognizes interrupts as one of two types only: a normal interrupt request (IRQ) or a fast interrupt request (FIQ). All the interrupts can be masked separately.

Wereley, ¶154; Ex. 18 (GEHCDEL129737, at GEHCDEL129796).

Next, there is no genuine dispute that the CPU allows the “interchangeable modular component to independently perform operations in response to instructions over the system bus.” The Court did not construe this term so the plain and ordinary meaning as understood by a POSITA is applied. *See EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 109 (D. Del. 2016). The plain English of this claim language refers to the modules themselves, and requires that the particular module’s operations be independent from the operations of other modules installed in the system. This language also requires that the operations be in response to instructions received over the bus. *See also* Wereley, ¶157.

A Bio-Rad witness, Mr. Iovanni, confirmed that [REDACTED]

[REDACTED]. For example, Mr. Iovanni confirmed that [REDACTED].

Wereley, ¶¶158-159; Ex. 2 (Iovanni Tr.) 105:9-22. Mr. Bland confirmed this. *See* Wereley, ¶158; Ex. 10 (Bland Tr.) 107:13-108:13.

Finally, each module receives instructions over the bus from the master control unit. Cytiva’s source code expert reviewed the NGC’s source code and confirmed that each module receives instructions. Decl. of Nenad Vukicevic (“Vukicevic”), ¶¶5-9. [REDACTED]

[REDACTED] *Id.* ¶7. For example, [REDACTED]

[REDACTED] *Id.* Similarly,

[REDACTED] *Id.*

¶9.

Furthermore, testimony from Bio-Rad witnesses confirms that each module receives commands from the master control unit over a system bus. For example, a Bio-Rad witness explained that [REDACTED]

[REDACTED] Ex. 10 (Bland Tr.) 106:20-107:1; *see also*

105:18-108:13 (explaining generally how modules receive commands from the master control unit). Further, Bio-Rad specifications for each module state that each module communicates with the single board computer (master control unit) via a bus, which Bio-Rad witnesses confirmed. *See* Wereley, ¶¶79-80; Ex. 13 (BRGE0096083); Ex. 14 (BRGEDEL000450748); Ex. 10 (Bland Tr.) 144:1-11.

Accordingly, there is no genuine dispute that this limitation is met.

12. “wherein the master control unit is arranged to automatically identify interchangeable modular components”

There is no genuine dispute that all NGC models contain this limitation. The NGC’s Instrument Guide explains that “[e]ach module has a unique electronic ID that enables the system to recognize its function when the module is placed into a

bay. For example the system can distinguish between a sample inject valve module and a sample inlet valve module even though they both occupy a single-wide slot.” Wereley, ¶164; Ex. 5, p. 19. A Bio-Rad specification further explains that [REDACTED]

[REDACTED] Wereley, ¶164;

Ex. 12 (BRGEDEL401629). Bio-Rad’s witness, Mr. Wayne Bland, confirmed that the “system” includes the master control unit and that [REDACTED]

[REDACTED]. See Ex. 10 (Bland Depo. Tr.) 81:19-85:22. This is further confirmed by the NGC’s source code. The source code contains [REDACTED]

[REDACTED]. See Vukicevic, ¶10. [REDACTED]
[REDACTED] *Id.* Accordingly, there is no genuine dispute that this limitation is met.

13. “wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least three of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and”

The “adapted to accommodate” claim language requires only that the housing have the ability to have the listed items inserted therein. The language does not require the listed items actually be present, only that the housing can accommodate them. There is no genuine dispute that all NGC models can “accommodate” the

listed items. First, each NGC model can accommodate any module, regardless of whether a module comes standard with a particular system. Wereley, ¶¶169-170, Ex. 5, p 87-88. For example, while the NGC Quest comes standard with a sample inject valve module, a customer can purchase additional valve modules and install them into the system, *e.g.*, a pH valve module. *Id.* Therefore, all NGC models are able to accommodate at least two fluid control valves of different configurations. Additionally, because each NGC model comes standard with a UV detector module, each is also able to accommodate at least one sensor unit, since a POSITA would understand that the UV detector module is a “sensor unit.” *Id.*

Finally, this element requires that “at least three of the pump, the sensor unit and the fluid control valves are interchangeable modular components. As explained in Section V.B.4, all NGC models come with two system pump modules and a sample inject valve module, each of which are interchangeable modular components. Thus, “at least three” of the listed items qualify as interchangeable modular components.¹⁰

¹⁰ As will be discussed in Section V.C.3, all NGC models come standard with a UV monitor module, which are also interchangeable modular components. Note also that each of Bio-Rad’s NGC models can “accommodate” many other modules, as a user can either fill an empty bay with a new module or move modules from one bay to another. Moreover, the claim does not require that all of the modules the system can “accommodate” be “interchangeable modular components.”

14. “wherein the system is capable of performing automated liquid chromatography”

There is no genuine dispute that all NGC models contain this limitation for the same reason discussed above, in Section V.B.1, concerning the preamble.

C. Cytiva is Entitled to Summary Judgment that Bio-Rad Infringes Claim 1 of the ’589 Patent

1. “An automated liquid chromatography system comprising”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.1.

2. “a housing unit and”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.2. Note that while claim 1 of the ’420 patent requires “a housing” and this claim requires a “housing unit,” there is no appreciable difference between the terms.

3. “at least four modular fluid handling units”

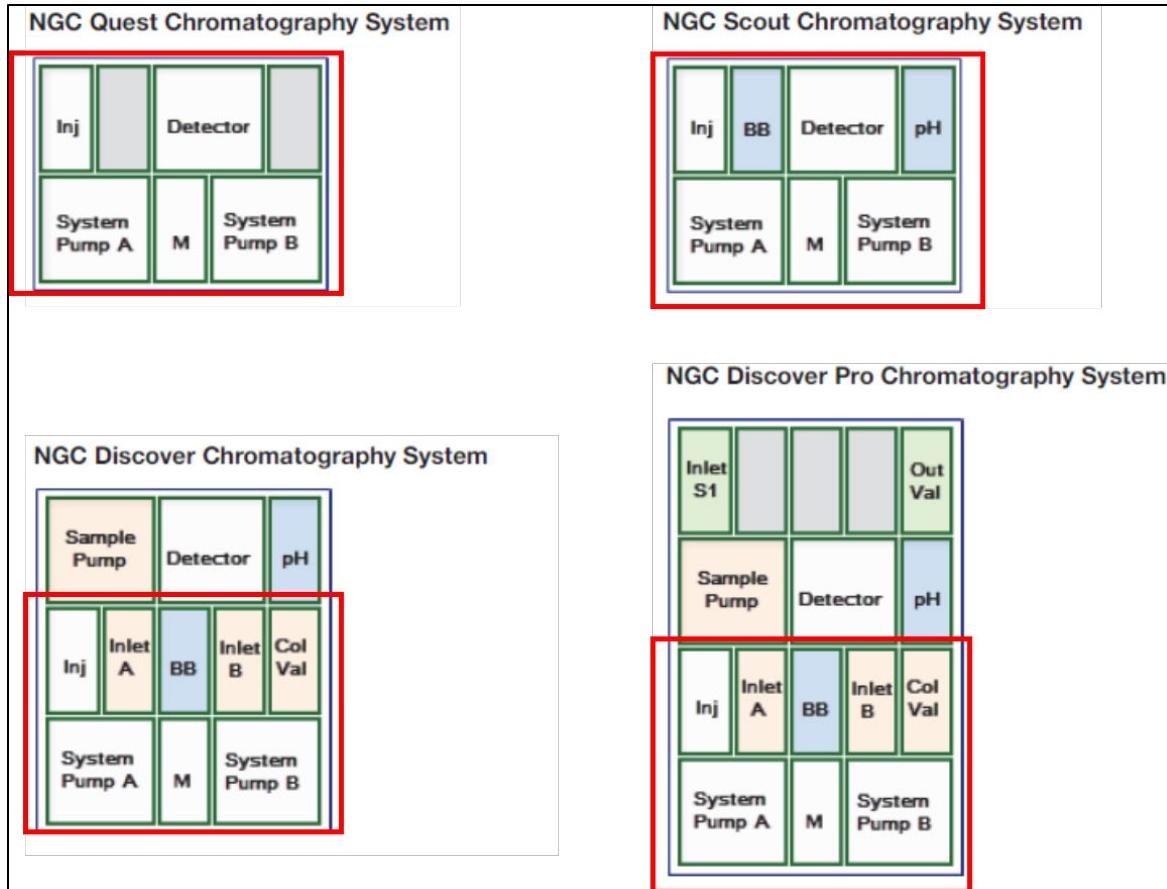
There is no genuine dispute that all NGC models contain this limitation. The Court construed the term “modular fluid handling unit” to be a “fluid handling unit that has a standardized size and shape that allows it to be exchanged with another fluid handling unit.” D.I. 75-1, at 2. As explained above, in Section V.B.4, all NGC models come standard with two system pump modules and a sample inject module,

each of which satisfy the “modular fluid handling unit” construction.¹¹ All NGC models also come standard with either a single or multi-wavelength UV detector module. *See Wereley, ¶215, Ex. 5, p 66.* Bio-Rad’s UV detector modules are also “modular fluid handling units” under the Court’s construction, as they each have a standardized size and shape (double-wide modules) that allows them to be exchanged with another component. *See Wereley, ¶217.*

4. **“wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array”**

There is no genuine dispute that all NGC models contain this limitation. First, the housing unit of each has a “plurality of receiving portions,” which is seen in the annotated figures from Bio-Rad’s Instrument Guide:

¹¹ Note there is no effective difference between the constructions of “interchangeable modular component,” recited in claim 1 of the ’420 patent, and “modular fluid handling unit,” recited in claim 1 of the ’589 patent.



See Wereley, ¶221, Ex. 5, p. 90-91. Bio-Rad's Instrument Guide also demonstrates how each receiving position may be converted from a single-wide to a double-wide position in order to accommodate different sized modules. Ex. 5, pp. 237-238. These receiving positions are arranged in two dimensional array. *See* Wereley, ¶223.

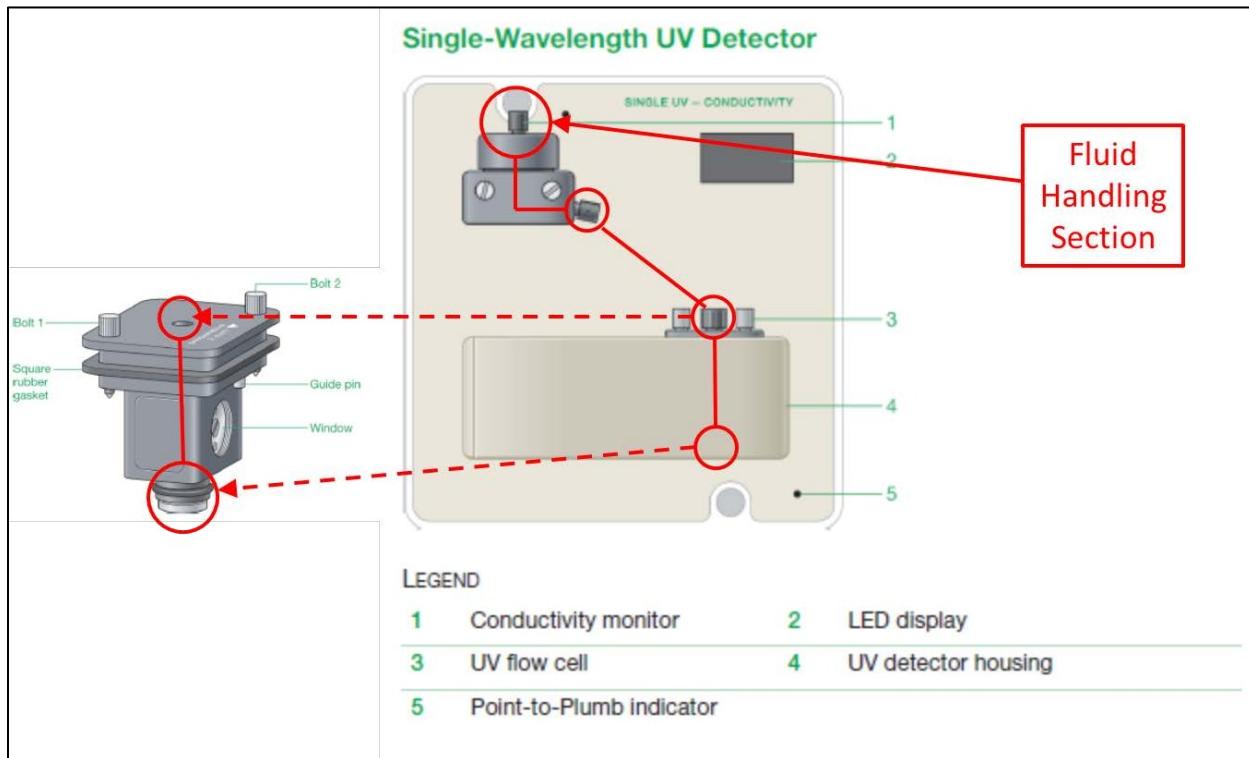
Next, each of the four modular fluid handling units has “a fluid handling section.” The Court construed “a fluid handling section” to be “a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components.” D.I. 75-1, at 3. Because the Court gave the same construction to “a fluid handling section” and “a fluidics section,” the NGC’s sample

inject valve and two system pump modules each have “a fluid handling section,” which is external to the housing unit. *See supra* Section V.B.5.

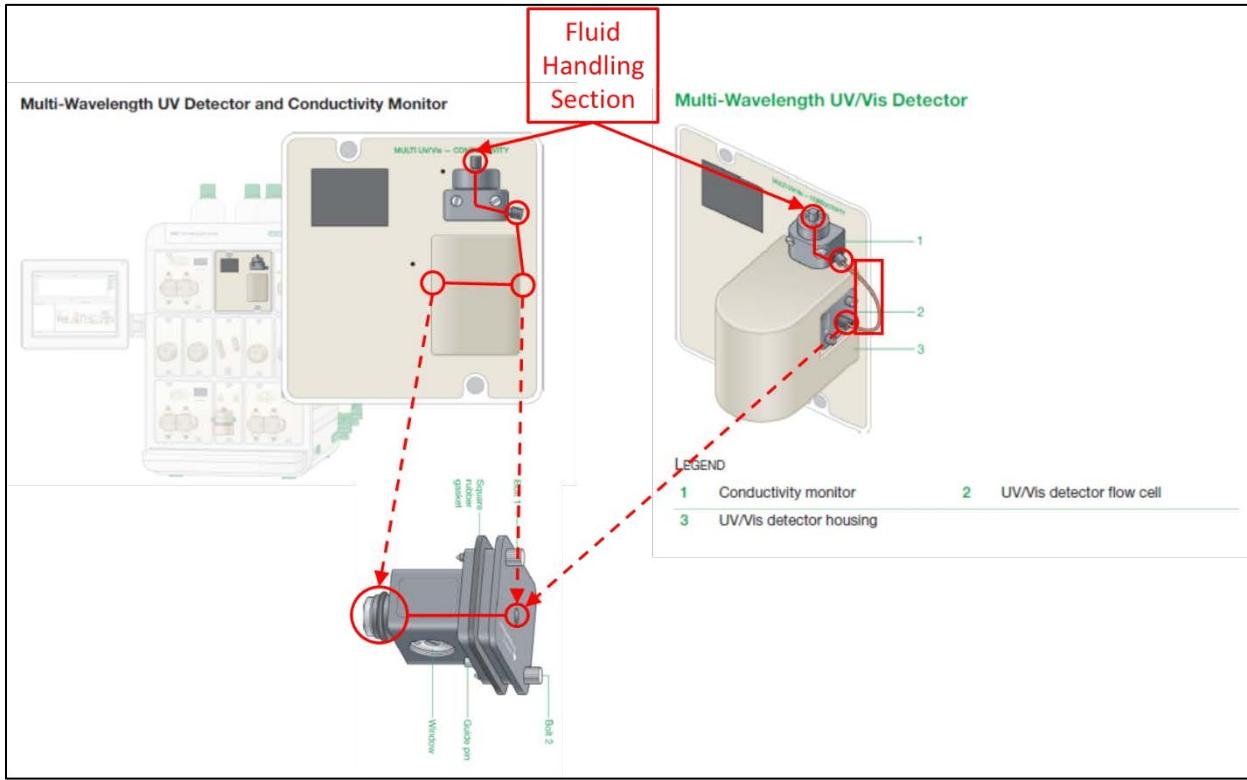
Additionally, each of Bio-Rad’s UV monitor modules have “a fluid handling section.” The specification for each UV monitor module states that [REDACTED]

[REDACTED] Wereley, ¶226, Exs. 19

(BRGEDEL282560), 20 (BRGEDEL281538). A Bio-Rad employee, Mr. Chapman, confirmed that the modules meet this specification. *See* Ex. 3 (Chapman Tr.) 532:4-534:17. The figures below excerpted from Bio-Rad’s documentation have been annotated to show the external fluid handling section of the single-wavelength UV detector monitor module and the multi-wavelength UV detector monitor module, respectively:



Wereley, ¶234; Ex. 5, p. 67, 205.



Wereley, ¶235; Ex. 5, p. 66, 69, 205.

The fluid handling section of each of these modules include fluidic components like tubing inputs and outputs, valve components, pump components, flow cells, and other components through which fluid passes. Wereley, ¶236. The claim limitation further requires that the fluid handling section “does not include non-fluidics components.” While the annotated drawings are clear that the fluidics section contains only components involved in fluid transmission, Dr. Wereley confirmed that a POSITA would understand that to the extent there are non-fluidic components outside of the claimed non-fluidics section, those electronics are not part of the fluidics section. *See* Wereley, ¶237.

5. “wherein each modular fluid handling unit is configured for insertion into the receiving positions of the housing unit”

There is no genuine dispute that “each modular fluid handling unit is configured for insertion into the receiving positions of the housing unit.” Each of the two system pump modules, sample inject valve module, and UV detector modules “is configured for insertion into the receiving positions of the housing unit,” as the claim requires. Bio-Rad’s Instrument guide explains that “[t]he position of the module on the system can be changed to optimize the placement and minimize the length of tubing.” Wereley, ¶215, Ex. 5 p. 19. An NGC specification further explains how the NGC is designed such that modules [REDACTED]

[REDACTED] (Wereley, ¶215, Ex. 12 (BRGEDEL401642)) and that the system requires [REDACTED] (Wereley, ¶216, Ex. 12 (BRGEDEL401629)). This was confirmed by Bio-Rad’s Mr. Bland, who testified that “the modules are fully interchangeable with all bays within the -- the housing, so they could be moved in any location as many times as a user may want to configure them.” Wereley, ¶215, Ex. 10 (Bland Tr.) 98:13-101:1.

6. “wherein each modular fluid handling unit is ... is readily interchangeable amongst similarly sized and shaped receiving positions of the housing unit, such that positioning of the modular fluid handling unit with respect to other modular fluid handling units permits a fluid flow path to be readily modified, wherein the fluid flow path is formed by fluidic connections between the modular fluid handling units, and”

There is no genuine dispute that all NGC models contain this limitation. First, the Instrument Guide for the NGC explains that “[t]he position of the module on the system can be changed to optimize the placement and minimize the length of tubing, reducing the system swept volume:”



2 The NGC Instrument

The NGC instrument ships preassembled with the components necessary to perform gradient separations. The modular components slide into slots in the system known as *bays*. Some modules fit into single-wide bays while others require double-wide bays. Bays can be converted from one size to the other by adding or removing a center divider.

Each module has a unique electronic ID that enables the system to recognize its function when the module is placed into a bay. For example, the system can distinguish between a sample inject valve module and a sample inlet valve module even though they each occupy a single-wide slot.

The position of the module on the system can be changed to optimize the placement and minimize the length of tubing, reducing the system swept volume.

The physical location of a module can be easily identified in the overall flow scheme required to run the application through the ChromLab software. Prior to starting a run, ChromLab performs a system check to ensure that all the required modules are physically present on the instrument.

This chapter explains in detail the modules that make up the NGC instrument.

Wereley, ¶243; Ex. 5, p. 19 (annotated). The Instrument Guide for the NGC also provides detailed instructions for how a user can easily move modules between the claimed receiving positions:

Replacing or Repositioning Modules on the NGC Instruments

WARNING! Disconnect power to the NGC instrument before removing or repositioning any module. Do not attempt to service any component on the NGC instrument unless noted in this manual. Contact Bio-Rad for service requests.

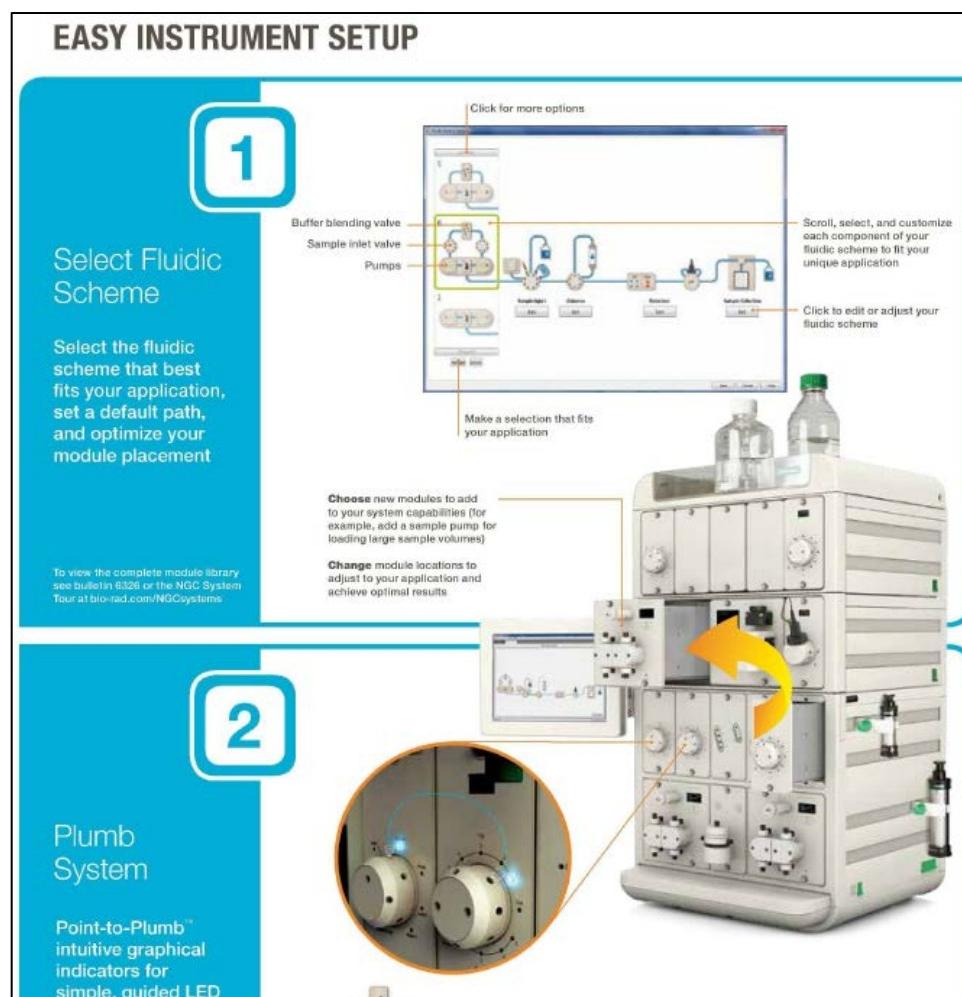
WARNING! To reduce the chance of liquid seeping into the instrument, all open bays must be filled with the NGC Blank module (catalog #788-4005). The NGC instrument will not operate if it detects a slot without a module inserted.

To replace or reposition modules on the NGC instruments

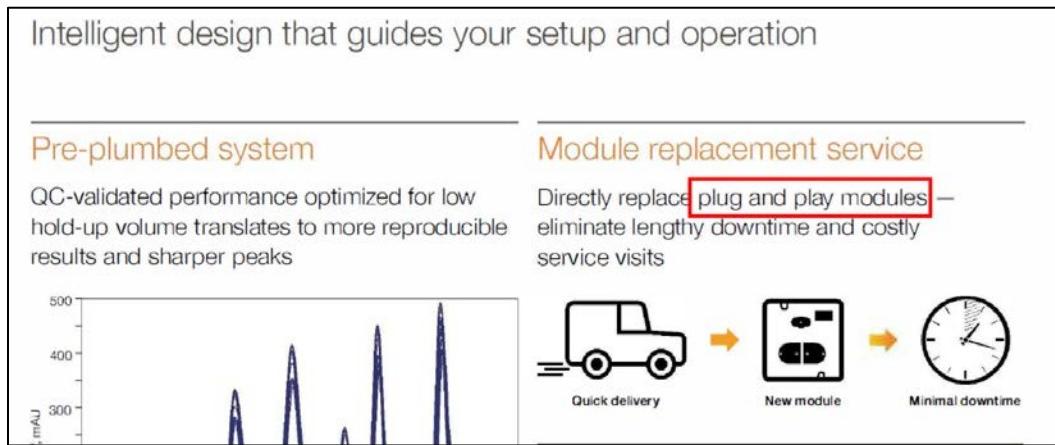
1. On the touch screen, select Shut Down on the dropdown menu to exit ChromLab and shut down the NGC instrument.
2. If necessary, disconnect all tubing lines to and from the module that you plan to replace or reposition.
3. Loosen the captive screws on the front of the installed module.
4. Firmly grasp both screws on the module and pull it forward out of its bay.

See Wereley; ¶244; Ex. 5, p. 233. *See also id.* at 234-239. A POSITA would understand that replacing and repositioning the NGC's modules would be easy and that the modules are “readily interchangeable,” as required by the claim. *See* Wereley; ¶244. This same section of the Instrument Guide provides instructions for converting the size of bays such that two single-wide bays can accommodate a module requiring a double-wide bay and vice versa. *See* Wereley, ¶¶245-246; Ex. 5, pp. 237-238.

Additionally, “positioning of the modular fluid handling unit with respect to other modular fluid handling units permits a fluid flow path to be readily modified,” just as claimed. As explained above, the NGC’s modules can be repositioned to “minimize the length of tubing, reducing the system swept volume.” Wereley, ¶243; Ex. 5, p. 19. Furthermore, a Bio-Rad marketing document touting “Easy System Setup” illustrates the repositioning of modules and states that users can “[c]hange module locations to adjust to your application and achieve optimal results:”



Wereley, ¶247; Ex. 21 (BRGEDEL293539). This same document further refers to Bio-Rad's modules as “plug and play:”

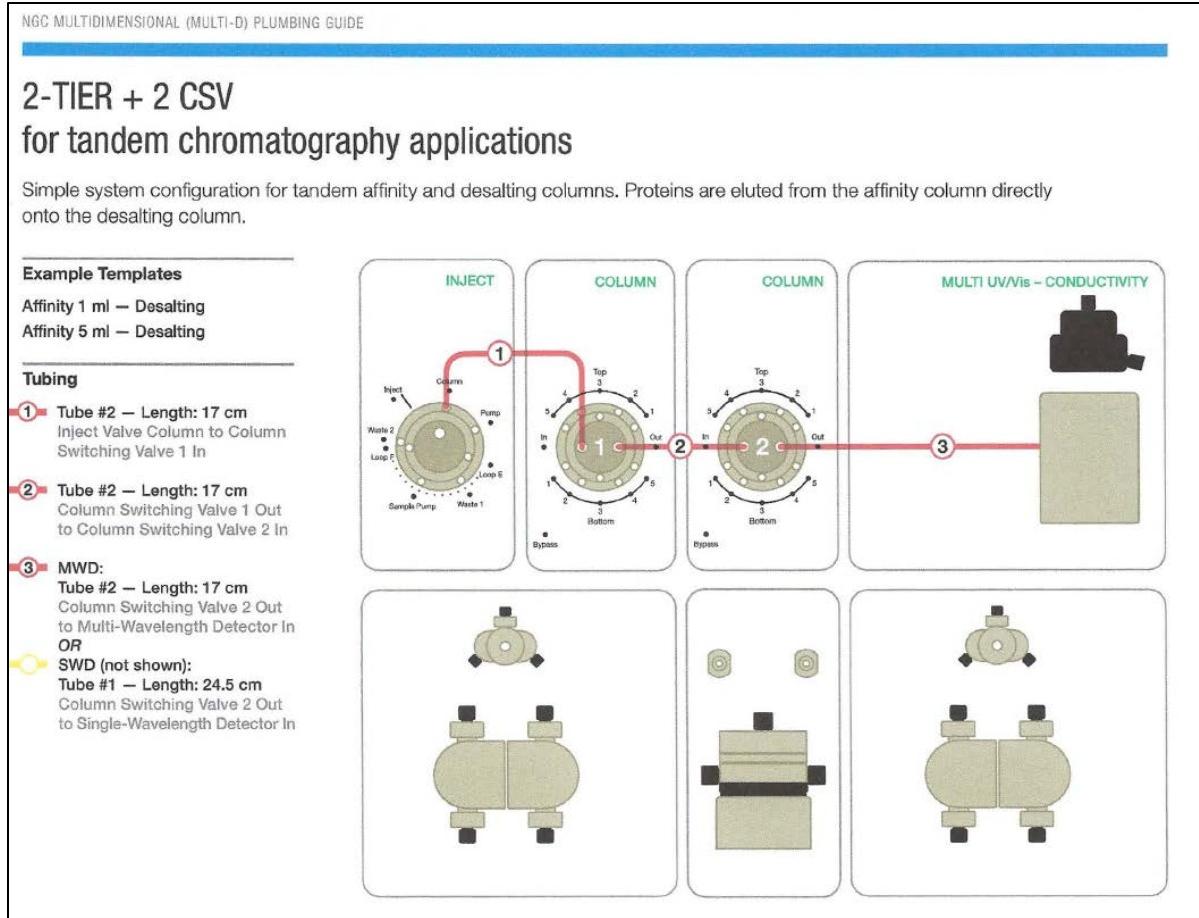


Wereley, ¶247; Ex. 21 (BRGEDEL293542).

The NGC Plumbing Guide (Ex. 22) also explains that modules can be placed in different receiving positions:

This guide is designed to help plumb your NGC System for multidimensional (Multi-D) chromatography applications. These techniques can help enhance sample recovery and improve productivity by minimizing the steps and time required for protein purification. In addition, it shows the optimal locations for module placement to minimize tubing length and swept volume.

Wereley, ¶248; Ex. 22, p. 2. The same document illustrates an arrangement of modules that differs from the standard configurations of the NGC:



Wereley, ¶248; Ex. 22, p. 3. Moreover, Mr. Bland testified that users are able to customize the arrangement of the NGC's modules. Ex. 10 (Bland Tr.) 100:8-101:1.

Lastly, each NGC model forms a fluid flow path “by fluidic connections between the modular fluid handling units.” The fluid handling section of the system pump modules, sample inject valve module, and UV monitor modules each have inputs and outputs. There is tubing between these modules that connects the inputs and outputs and thus creates a “fluid flow path,” just as claimed. Wereley, ¶250.

7. “wherein each modular fluid handling unit ... includes a CPU for independently performing fluid control operations in response to instructions over a system BUS”

There is no genuine dispute that all NGC models contain this limitation. This limitation is met for the same reason discussed above, in Section V.B.11.

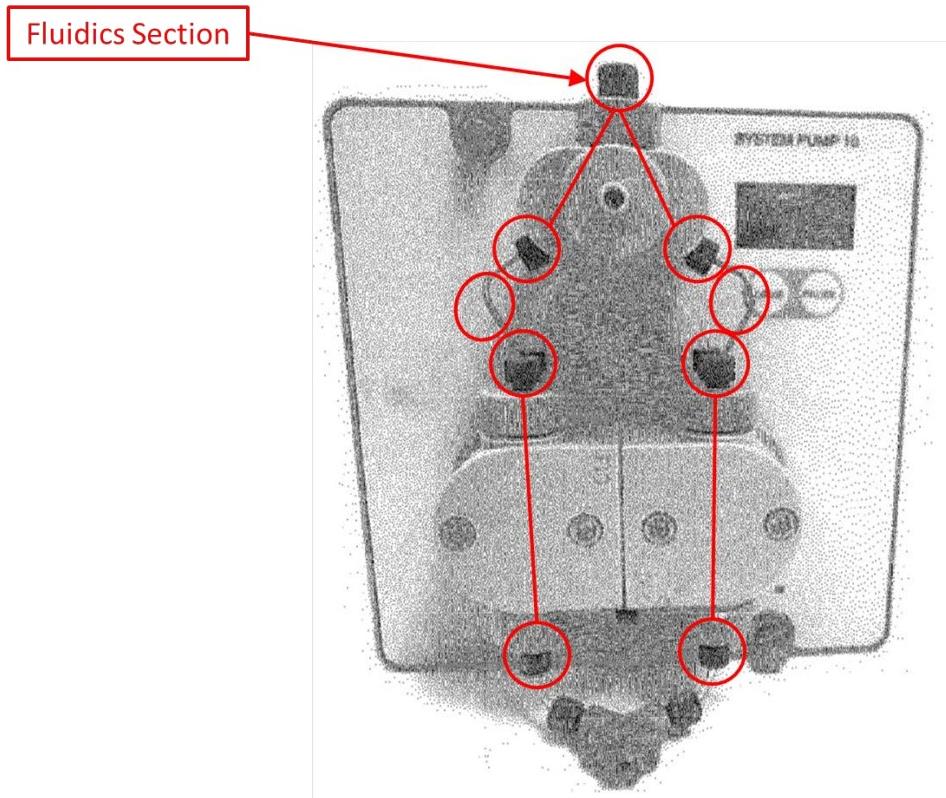
D. Cytiva is Entitled to Summary Judgment that Bio-Rad Infringes Claim 14 of the ’591 Patent

There is no genuine dispute that all NGC models contain this claim. Dependent claim 14 depends from dependent claim 13 which depends from independent claim 1. The only difference between claim 1 of the ’591 patent and claim 1 of the ’420 patent is that the former requires only two fluid handling units arranged as interchangeable module components and they need not be arranged in a two dimensional array Wereley, ¶¶264-265.

Accordingly, all NGC models satisfy each limitation of claim 1 of the ’591 for the same reasons explained above in Section V.A.

Claim 13, from which claim 14 depends, requires that the “fluidics section” of each of the two interchangeable modular component recited in claim 1 have “one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path and wherein all fluid connectors are on a wet side of the panel member.” As explained above, all NGC models come with two system pump modules, each of which are interchangeable modular components. *See supra* Section V.B.4. The annotated figure above in Section V.B.5 shows that the two system pump

modules have “fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path.” Another is shown below:



Wereley, ¶286, Ex. 23 (BRGEDEL1507). All the ports (red-circled) connect the module to the liquid chromatography fluid path. As seen in the above image, the “fluid connectors” are “on the external side of the panel member.”

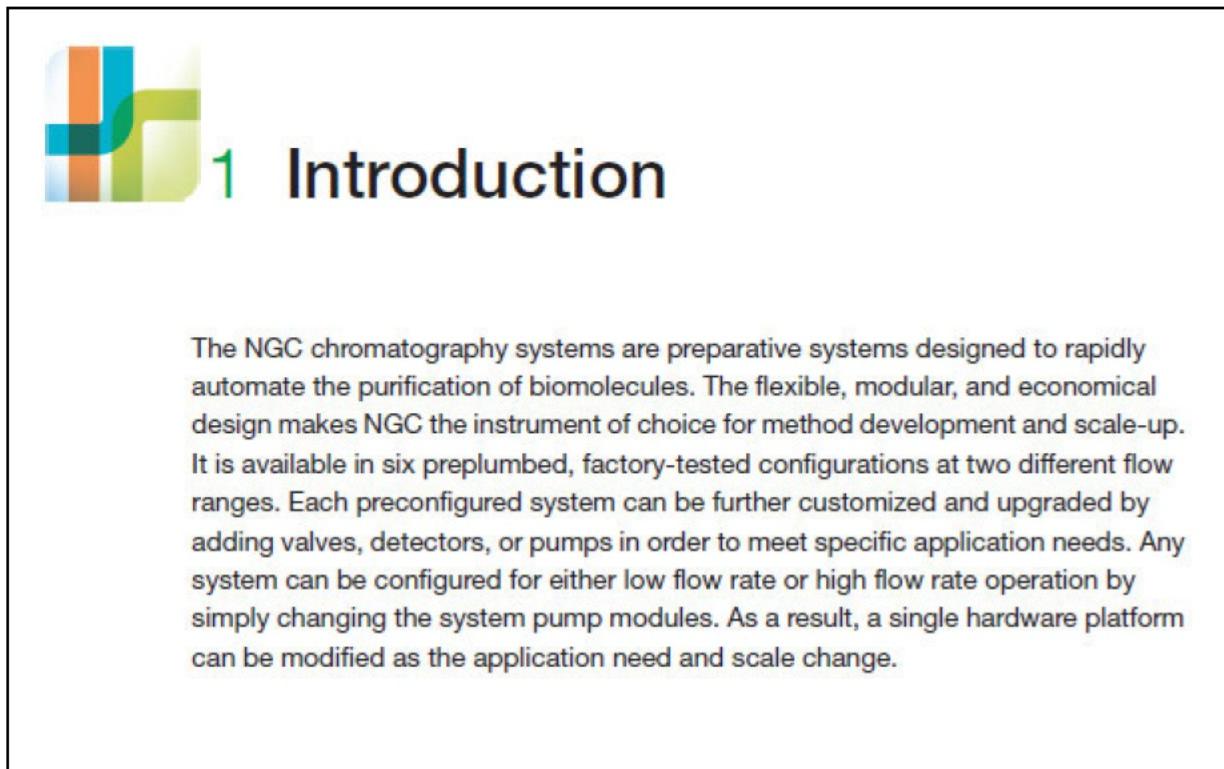
Lastly, claim 14 requires that the “liquid chromatography fluid path being reconfigurable by moving the interchangeable modular components freely between the component receiving positions.” As explained above, in Section V.C.6 in regards to claim 1 of the ’589 patent, “each modular fluid handling unit ...is readily interchangeable” and by doing so the “fluid flow path [is] readily modified.”

Because the modules can be “readily” interchanged, they can also be “freely” interchanged. Accordingly, this limitation is met for the same reasons discussed in Section V.C.6.

E. Cytiva is Entitled to Summary Judgment that Bio-Rad Infringes Claim 16 of the ’124 Patent

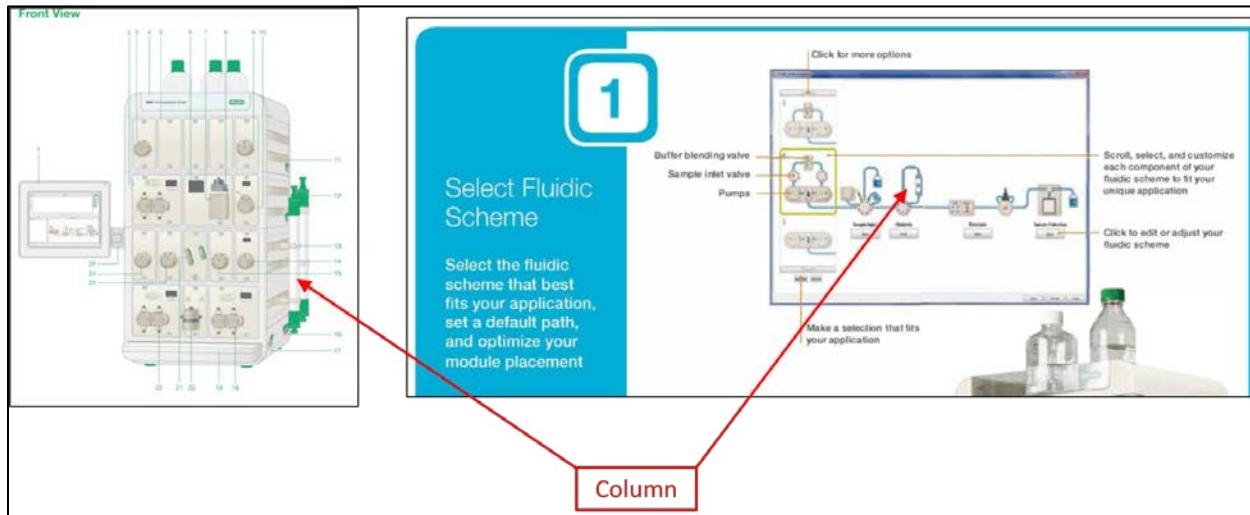
1. “A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising”

There is no genuine dispute that all NGC models contain this limitation. First, the NGC’s Instrument Guide explains that it is a liquid chromatography system and that the system “rapidly automates” the purification of biomolecules:



Wereley ¶295; Ex. 5, p. 11.

Each NGC model are “arranged to provide a controlled fluid flow through a chromatography column.” When interconnecting the fluid inputs and outputs on the NGC, fluid will pass through the system and is thus being “controlled.” As illustrated below in the annotated figures, fluids will pass through a chromatography column:



Wereley, ¶¶295-296, Ex. 5 (left), p. 22 and Ex. 21, p. BRGEDEL293539 (right).

2. “a housing and”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.2, concerning the “housing” of claim 1 of the ’420 patent.

3. “two or more interchangeable fluid handling units”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.4, concerning the “three or more fluid handling units arranged as interchangeable modular components” of claim 1 of the ’420 patent.

4. “the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable units”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.9, concerning the “liquid handling panel” of claim 1 of the ’420 patent.

5. “wherein said units are arranged as interchangeable modular components”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.4, concerning the “three or more fluid handling units arranged as interchangeable modular components” of claim 1 of the ’420 patent. Because claim 16 recites the need for only two interchangeable modular components, it is broader, and all NGC models fall within the scope of this claim element for the same reasons as discussed in Section V.B.4.

6. The interchangeable modular components include “a fluidics section”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.5, concerning the “fluidics section” of claim 1 of the ’420 patent.

7. The interchangeable modular components include “a non fluidics section in turn comprising electronics or electrical components or control means”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.6 , concerning the “non-fluidics section” of claim 1 of the ’420 patent.

8. The interchangeable modular components include “a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Section V.B.8, concerning the “panel member arranged to separate the fluidics section from the non fluidics section” of claim 1 of the ’420 patent.

Additionally, the panel member of each NGC module is “arranged … for attachment of the modular component to a component position of the liquid handling panel.” The panel member for each of the NGC modules comprises, among other things, what Bio-Rad refers to as a “front plate” having an “overlay” affixed to the front plate portion on the external side of the system. *See Ex. 10 (Bland Tr.) 151:4-155:21.* Mr. Chapman confirmed that “the metallic face plate is part of the structural housing for each individual valve or detector. And, it enables the mounting of any components that need to be exterior to the internal workings, such as the inject port,

the valves, all of the LEDs, which are external to the inner workings of the system.”

Ex. 3 (Chapman Tr.) 387:10-17. This testimony is corroborated by Bio-Rad’s Instrument Guide, which explains how to affix a module to the housing:

9. Place the module into the open bay and gently push it in as far as it will go.

Note: Each module has an alignment pin on the back to ensure that it aligns correctly with the main communication board.

10. Ensure that the screw holes on the module align with the screw holes on the bay.
11. Insert the screws that shipped with the module into the screw holes.
12. Tighten the screws to secure the module.

Wereley, ¶305; Ex. 5, p. 235.

9. “wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Sections V.B.8 and V.B.9, concerning the “panel member arranged to separate the fluidics section from the non fluidics section” and “liquid handling panel,” respectively, of claim 1 of the ’420 patent.

10. “respective non fluidics sections are internal to the housing”

There is no genuine dispute that all NGC models contain this limitation for the same reasons discussed above, in Sections V.B.8 and V.B.9, concerning the “panel member arranged to separate the fluidics section from the non fluidics section” and “liquid handling panel,” respectively, of claim 1 of the ’420 patent.

VI. CONCLUSION

For the reasons provided above, Cytiva respectfully submits that the Court should grant this motion for summary judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to the Court's November 6, 2019 Standing Order, I hereby confirm that this brief complies with the type and number limitations set forth in the Standing Order. I certify that this document contains 7,546 words, which were counted using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count does not include the cover page, table of contents and authorities, or the counsel blocks font. The total number of words in all of Plaintiffs' case-dispositive and *Daubert* briefs is less than 12,500 words, calculated in the above manner.

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